Considerations for Interpretation of Tuberculosis Test Results and Administration of the mRNA COVID-19 Vaccine

Updated as of January 14, 2021
Please note that as the situation develops, this guidance will be updated with any changes.

The guidance below should assist with questions regarding new hires and annual Tuberculosis (TB) testing among healthcare workers as COVID-19 vaccines are being administered across the state. The following information is taken directly from the Centers for Disease Control and Prevention's (CDC's) Interim Clinical Considerations document on mRNA COVID-19 Vaccines, followed by guidance from the CDC/Division of TB Elimination (in italics), and suggested recommendations from the KY TB Prevention and Control Program:

Inactive vaccines do not interfere with tuberculosis (TB) test results. **There is no immunologic reason to believe either a Tuberculin Skin Test (TST) (administered by intradermal placement of 0.1 cc of purified protein derivative) or blood draw for interferon gamma release assay (IGRA) would affect the safety or effectiveness of mRNA COVID-19 vaccines**. We have no data to inform the impact of the COVID-19 mRNA vaccines on either TB test for infection (i.e., TST or IGRA).

For healthcare personnel or patients who require baseline TB testing (at onboarding or entry into facilities) at the same time they are to receive an mRNA COVID-19 vaccine:

- Perform TB symptom screening on all healthcare personnel or patients.
- If utilizing the IGRA, draw for interferon gamma release assay prior to COVID-19 vaccination.
- If utilizing the TST, place prior to COVID-19 vaccination.
- If vaccination has been given and testing needs to be performed, defer TST or IGRA until 4 weeks after the COVID-19 vaccine 2-dose completion.
    - All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.

For healthcare personnel who require testing for other reasons:

- Perform TB symptom screening on all healthcare personnel.
- Test for infection should be done before or at the same time as the administration of COVID-19 vaccination. If this is not possible, prioritization of test for TB infection needs to be weighed with the importance of receiving COVID-19 vaccination based on potential COVID-19 exposures and TB risk factors.
    - Healthcare personnel with high-risk conditions for TB progression should be fully evaluated as soon as possible.
    - Healthcare personnel without high-risk conditions for TB progression should proceed with contact tracing (i.e., symptom screening, chest radiograph or other imaging, specimen for microbiologic evaluation) but delay test for TB infection (TST or IGRA) if prioritized for receiving COVID-19 vaccination.

- **All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.**[1]

Administratively, ***the expedient approach would be to test for M. tuberculosis as required, when required, regardless of the vaccine schedule. After the administrative requirements are met****, the issues of medical care, infection control, and public health can be parsed:*

1. *TST and IGRA are not known to pose any additional risk of harm around mRNA COVID-19 vaccination.*
2. *A positive result from TST or IGRA after mRNA COVID-19 vaccination should have the same degree of reliability as a positive result without the vaccination.*
3. *A negative result from TST or IGRA might be less reliable after mRNA COVID-19 vaccination; evidence has not been gathered yet as to whether this is true. In situations when testing was done for administrative requirements, but a potentially more reliable result is needed, testing could be repeated after the waiting period for the vaccine, as decided by policy or on a patient-by-patient basis with expert consultation.*
    a. *As a reminder, repeating a TST can lead to boosting. Studies in older adults provide evidence that boosting can appear after up to five doses of TST. Boosting complicates the interpretation of a TST result.*
    b. *IGRA is not complicated by boosting because the patient is not exposed to an antigen.*
4. *For institutional settings, practitioners need to be reminded that TST and IGRA are ineffective tools for finding active TB disease, because of insufficient sensitivity and specificity, regardless of COVID-19 vaccination. The main reasons for testing in institutional settings should be surveillance and infection control; chest radiography and symptom interviews should be used for active case finding.*

There are no data on the impact of the COVID-19 mRNA vaccines on either the tuberculin skin test (TST) or the interferon gamma release assay (IGRA). ***If COVID-19 mRNA vaccination has already occurred****,* ***defer TST or IGRA until 4 weeks after completion of 2-dose COVID-19 mRNA vaccination****; there are no data at present to support adopting different approaches for the Moderna and Pfizer preparations.*

In TB contact investigations, the number of circumstances and permutations are likely to be so numerous as to preclude a fixed algorithm. For example, the ages of the TB contacts, their underlying medical conditions, and the timing of mRNA COVID-19 vaccination will become part of a decision matrix. Therefore, when mRNA COVID-19 vaccination overlaps with TB contact investigations, the decisions should be made patient by patient. Testing generally should not be deferred because of mRNA COVID-19 vaccination. Some state TB control programs already have policies about deferring the initial test for "low-priority" contacts. The above precaution about boosting with TST should be considered if tests are repeated because a potentially more reliable result is needed.[2]

Recommendations from the Kentucky TB Prevention and Control Program

As previously stated in the guidance from the CDC, all potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.

For Healthcare Workers in health facilities or settings licensed under KRS Chapter 216B or KRS Chapter 333:

If facilities choose to delay their infection control activities as stated in "TB Testing for Healthcare Workers" 902 KAR 20:205/section 2, the site infection control plan needs to provide a date of onset and a time-certain end of the temporary pathway determined by your facility (four months from date of onset is recommended). If a site chooses not to delay, and proceed with the site's current infection control plan, the site will test when it is required regardless of the vaccine schedule.

For Residents of Long Term Care Settings licensed under KRS Chapter 216B or KRS Chapter 333:

In the instance of any individual needing admission to a long term care setting, then proceed with a medical evaluation and documentation of non-infectious status for M. tuberculosis as stated by "TB Testing of Residents of Long Term Care Settings" 902 KAR 20:200/section 4.

If the facility decides to delay testing of a resident of a long term care setting as stated in 902 KAR 20:200/section 8, the site infection control plan needs to provide a date of onset and a time-certain end of the temporary pathway determined by your facility (four months from date of onset is recommended). If a site chooses not to delay, and proceed with the site's current infection control plan, the site will test when it is required regardless of the vaccine schedule.

Sources:

1. Centers for Disease Control and Prevention – Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. See *Laboratory testing* section. https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

2. Direct Correspondence from Terence Chorba, MD, DSc, LLM, MPH, MPA, FACP, FIDSA, Chief, Field Services Branch Division of Tuberculosis Elimination National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention